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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

March 9, 2015

The Honorable Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Hamburg:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is continuing its examination of the U.S. public health response to seasonal influenza. We appreciated FDA's participation and testimony at the hearing on February 3, 2015.

The committee seeks further information regarding the U.S. public health response to seasonal influenza. We believe understanding the lessons from this influenza season could improve the U.S. public health response in the future, particularly to a severe influenza season with a mismatched vaccine, and possibly save thousands of lives.

To assist the committee's inquiry, please respond to the following questions by March 23, 2015:

1. Has FDA ever approved a monovalent influenza vaccine to target a drifted seasonal influenza strain? If so, when? What were the circumstances? What legal authorities were required for the approval?

2. Has there ever been a delay in the production of an influenza vaccine because a vaccine manufacturer was waiting for FDA to provide the reagents? If so, when? What were the circumstances?

3. In August 2010, the President's Council of Advisors on Science and Technology (PCAST) issued a report on reengineering the influenza vaccine production enterprise. The report recommended that the FDA should develop and issue a guidance document that defines a clear regulatory pathway for the approval of adjuvants. What actions, if any, has FDA taken to implement this recommendation?

4. The PCAST report also recommended that FDA should develop a well-defined regulatory process for introducing alternative assays for seasonal influenza vaccines. What actions, if any, has FDA taken to implement this recommendation? Have any alternative assays for flu vaccines been approved in the last three years?

5. The PCAST report recommended that FDA should define a regulatory process to guide development and implementation for sterility testing of influenza vaccines. Has FDA implemented this recommendation?

If you have any questions regarding this request, please contact Alan Slobodin with the committee staff at (202) 225-2927 and Elizabeth Letter of the Democratic committee staff at (202) 225-3641.

Sincerely,

Tim Murphy
Chairman
Subcommittee on Oversight
and Investigations

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

Cc:

The Honorable Fred Upton, Chairman

The Honorable Frank Pallone, Jr., Ranking Member